

### **DETAILED ACTION**

This Office Action is responsive to Applicant's Amendment-After Non-Final Rejection, filed February 3, 2011. As filed, Claims 1 & 3-46 are pending; of which, Claims 3, 18-21, 23, 36, & 47 are currently amended. Claims 2 & 47 are cancelled.

#### ***Response to Amendment***

Applicant's amendments to Claims 3, 18-21, 23, 36, & 47 have been fully considered and are entered. The status for each of the rejections and/or objections in the Office Action mailed October 12, 2010 is set out below.

The 103-prior art rejection of Claim 2 over US 6,528,660, WO 97/03959, and US 5,273,995 is withdrawn per cancellation of Claim 2.

The 112-indefinite rejection of Claim 47 as being an omnibus claim is withdrawn per cancellation of Claim 47.

The 112-indefinite rejection of Claims 3 & 4 for lacking antecedent basis is withdrawn per amendment.

The objection to Claims 18, 20, 21, 23, & 36 for being improper dependent claims is withdrawn per amendment.

The objection to Claims 19-21 is withdrawn.

#### ***Examiner's Amendment***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided

by 37 CFR § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with James DeYonker on April 8, 2011.

The application has been amended as follows:

- 1.** In Claim 26, ***after*** “. . . suspended in 15 to 25 volumes” and ***before*** “of a mixture of methanol and water . . .” ***delete*** “(w.r.t. weight of atorvastatin calcium)” and ***insert*** - - (with respect to the weight of atorvastatin calcium) - -.
- 2.** In Claim 27, ***after*** “. . . suspended in 15 to 25 volumes” and ***before*** “of a mixture of methanol and water . . .” ***delete*** “(w.r.t. weight of atorvastatin calcium)” and ***insert*** - - (with respect to the weight of atorvastatin calcium) - -.
- 3.** ***Delete/Cancel*** Claim 35.
- 4.** ***Add*** a new Claim 48 and ***insert*** - -

48. (New) The process of claim 1, wherein the conversion to amorphous form comprises:

  - a) dissolving crystalline atorvastatin calcium and an antioxidant in a solvent;
  - b) adding the atorvastatin calcium and antioxidant solution to an antisolvent; and
  - c) separating precipitated, amorphous atorvastatin calcium from the resulting suspension to obtain stabilized, amorphous atorvastatin calcium. - - .
- 5.** ***Add*** a new Claim 49 and ***insert*** - -

49. (New) The process of claim 1, wherein the conversion to amorphous form comprises:

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- a) dissolving crystalline atorvastatin calcium in a hydroxylic solvent;
- b) adding the obtained solution of atorvastatin calcium to a non-hydroxylic antisolvent, wherein the non-hydroxylic anti-solvent has a higher boiling point than the hydroxylic solvent;
- c) concentrating the solution so obtained to remove the hydroxylic solvent; and
- d) separating precipitated, amorphous atorvastatin calcium from the resulting suspension to obtain amorphous atorvastatin calcium. - - .

**6.** ***Add*** a new Claim 50 and ***insert*** - -

50. (New) The process of claim 48 or 49, wherein an antioxidant is added to the solution of atorvastatin calcium in hydroxylic solvent. - - .

***Conclusion***

Claims 1, 3-46, & 48-50 are allowed and renumbered Claims 1-48.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason M. Nolan whose telephone number is (571) 272-4356 and e-mail is [Jason.Nolan@uspto.gov](mailto:Jason.Nolan@uspto.gov). The examiner can normally be reached Monday - Friday (9:00AM - 5:30PM).

/Jason M. Nolan/

Examiner, Art Unit 1626